UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,661	03/08/2004	James G. Nadeau	P-4756D4	2586

26253 7590 09/15/2006

DAVID W. HIGHET, VP AND CHIEF IP COUNSEL
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC 110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,661	NADEAU ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *1-47,49,50 and 56-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48,51-55 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application
6)☐ Other: _____.

DETAILED ACTION

Priority

1. This application appears to be a division of Application No. 09/894,796, filed 28 June 2001. A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in an earlier or parent application is known as a divisional application or "division." The divisional application should set forth the portion of the earlier disclosure that is germane to the invention as claimed in the divisional application.

The '796 application became abandoned on 3 December 2003. The instant application was filed on 8 March 2004. Therefore, there was no copendency between the '796 and instant application. Copendency is a requirement for claiming priority to the earlier application. Because copendency did not exist, the instant application cannot claim priority to the '796 application.

It is noted that the Petition to accept unintentionally delayed claim for priority has been dismissed.

Therefore, the effective filing date for the instant application is 8 march 2004.

Preliminary Amendment

2. The amendments filed 8 March 2004, withdraw Claims 1-47, 49-50 and 56-59 and amend Claims 48 and 54.

Claims 48, 51-55 and 60 are currently pending.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 48, 51-55 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Nadeau et al (U.S. Patent No. 6,379,888, issued 30 April 2002).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claim 48, Nadeau et al disclose a set of oligonucleotides for detecting a target sequence comprising a first unlabeled signal primer comprising a single oligonucleotide having a 3' target binding sequence and a 5' adapter sequence, a second signal primer having an adapter sequence which is substantially identical to an adapter sequence of a first signal primer (Column 3, lines 58-65) and a reporter probe comprising a 5' reporter moiety and a 3' sequence which is substantially identical to the adapter sequence (Column 5, line 10-Column 6, line 3 and Column 9, lines 45-65).

Regarding Claim 51, Nadeau et al disclose the set wherein the reporter moiety is labeled (Column 5, lines 38-42).

Regarding Claim 52, Nadeau et al disclose the set wherein the reporter moiety is labeled with a fluorescent donor/quencher dye pair (Column 5, lines 38-42).

Regarding Claim 53, Nadeau et al disclose the set wherein the reporter moiety is selected from secondary structure (hairpin) and specialized sequences (complementary to adapter) (Column 5, lines 38-52).

Regarding Claim 54, Nadeau et al disclose the set wherein the reporter moiety is selected from G-Quartet and restriction sites (Column 5, lines 38-67).

Regarding Claim 55, Nadeau et al disclose the set wherein the reporter probe is non-extendable (Fig. 1).

Regarding Claim 60, Nadeau et al disclose a set of oligonucleotides for detecting a target sequence comprising a first unlabeled signal primer comprising a single oligonucleotide having a 3' target binding sequence and a 5' adapter sequence, a second signal primer having an adapter sequence which is different from an adapter sequence of a first signal primer (Column 4, lines 6-10) and a reporter probe comprising a 5' reporter moiety and a 3' sequence which is substantially identical to the adapter sequence (Column 5, line 10-Column 6, line 3 and Column 9, lines 45-65).

5. Claims 48 51-55 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Price et al (U.S. Patent No. 6,277, 582, issued 21 August 2001).

Price et al disclose and claim the set of oligonucleotides as instantly claimed (Claism 12-16).

6. Claims 48 51-55 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Wood et al (U.S. Patent No. 6,261, 785, issued 17 July 2001).

Wood et al disclose and claim the set of oligonucleotides as instantly claimed (Claims 1-16).

7. Claims 48 51-55 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Brink et al (U.S. Patent No. 6,251, 609, issued 26 June 2001).

Brink et al disclose and claim the set of oligonucleotides as instantly claimed (Claims 1-15).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 48 and 51-54 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nazarenko et al (U.S. Patent No. 5,866,336, issued 2 February 1999) in view of Walker et al (U.S. Patent No. 5,422,252, issued 6 June 1995).

Regarding Claim 48, Nazarenko et al teach a set of oligonucleotides for detecting a target sequence comprising: an unlabeled signal primer comprising a single oligonucleotide having a 3' target binding sequence and a 5' adapter sequence (primer 2 having adapter sequence A); and a reporter probe comprising a 5' reporter moiety and a 3' sequence which is substantially identical to the adapter sequence i.e. the hairpin primer having adapter sequence A (Column 24, line 55-Column 25, line 12 and Fig. 5). Nazarenko et al are silent regarding the set of oligonucleotides comprising a second signal primer. However, multiple signal primers were well known in the art at the time the claimed invention was made as taught by Walker et al who specifically teach multiple signal primers wherein a second signal primer has an adapter sequence which is substantially identical to the adapter sequence of the first signal primer (Column 5, lines 40-64 and Claim 8). Additionally, Walker et al teach that using signal primers have identical adapter sequences permits single-primer amplification of adapter-modified target strands (Column 7, lines 4-7). It would have been obvious to one of ordinary

skill in the art at the time the claimed invention was made to modify the set of oligonucleotides of Nazarenko et al by further adding a second signal primer where in the second signal primer has an adapter sequence substantially identical to the adapter sequence of the first sequence thereby permitting single-primer amplification of adapter-mediated target strands. One skilled in the art would have been motivated to provide for single-primer amplification because amplification of multiple target strands using a single primer eliminates the added time and costs of multiple primer synthesis or purchase. Therefore, the skilled practitioner in the art would have been motivated to perform single-primer amplification for the expected benefits of economy of time and reagent cost.

Regarding Claim 51, Nazarenko et al teach the oligonucleotides wherein the reporter moiety is labeled (Column 25, lines 13-17).

Regarding Claim 52, Nazarenko et al teach the oligonucleotides wherein the reporter moiety is labeled with a fluorescent donor quencher dye pair (Column 25, lines 13-17).

Regarding Claim 53, Nazarenko et al teach the oligonucleotides wherein the reporter moiety is a secondary structure or specialized sequences (Column 25, lines 13-17 and Fig. 5).

Regarding Claim 54, Nazarenko et al teach the oligonucleotides wherein the reporter moiety is a restriction endonuclease recognition site (Column 22, lines 41-50 and Claim 14).

Regarding Claim 60, Nazarenko et al teach a set of oligonucleotides for detecting a target sequence comprising: an unlabeled signal primer comprising a single oligonucleotide having a 3' target binding sequence and a 5' adapter sequence (primer 2 having adapter sequence A); and a reporter probe comprising a 5' reporter moiety and a 3' sequence which is substantially identical to the adapter sequence i.e. the hairpin primer having adapter sequence A (Column 24, line 55-Column 25, line 12 and Fig. 5) but they are silent regarding the set of oligonucleotides comprising a second signal primer. However, multiple signal primers were well known in the art at the time the claimed invention was made as taught by Walker et al who specifically teach multiple signal primers wherein a second signal primer has an adapter

sequence which is different from to the adapter sequence of the first signal primer i.e. each adapter is specific for each target end (Column 5, lines 40-64) whereby amplification of adapter-modified targets is adapter-specific (Column 6, line 64-Column 7, line 4). Additionally, Walker et al teach that different adapter sequences permit modification and amplification of multiple targets simultaneously within a single reaction mixture (Column 6, lines 64-68). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the differential adapter sequences taught by Walker et al to the signal primers of Nazarenko et al to thereby provide for modification and amplification of multiple target sequences within the same reaction mixture. One skilled in the art would have been motivated to modify and amplify multiple target sequences within the same reaction mixture because performing multiple reactions in a single reaction mixture is faster than multiple single reactions and the single reaction mixture assures that all target modifications and amplifications are performed under identical conditions. Therefore, the skilled practitioner in the art would have been motivated to perform multiple modifications and amplifications within a single reaction mixture for the expected benefits of speed and accuracy.

10. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nazarenko et al (U.S. Patent No. 5,866,336, issued 2 February 1999) in view of Walker et al (U.S. Patent No. 5,422,252, issued 6 June 1995) as applied to Claim 48 above and further in view of Tyagi et al (Nature Biotechnology, 1996, 14: 303-308).

Regarding Claim 55, Nazarenko et al teach the set of oligonucleotides for detecting a target sequence comprising: an unlabeled signal primer comprising a single oligonucleotide having a 3' target binding sequence and a 5' adapter sequence (primer 2 having adapter sequence A); and a reporter probe comprising a 5' reporter moiety and a 3' sequence which is substantially identical to the adapter sequence (hairpin primer having adapter sequence A(,

Column 24, line 55-Column 25, line 12 and Fig. 5) but they do not teach the reporter probe is non-extendible. Tyagi et al. teach oligonucleotides similar to Nazarenko et al. comprising: a primer and a reporter probe comprising a reporter moiety (page 305, last paragraph-page 306, first paragraph) wherein the reporter probe is non-extendable i.e. a seven-carbon carbon alkyl spacer which terminates in a primary amino group is attached to the 3' hydroxyl of the probe (page 304, right column, first full paragraph) and wherein the non-extendible reporter can be included with the amplification reactions without interfering with the amplification thereby permitting the progress of the amplification to be analyzed in real time (page 305, left column, last paragraph). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the reporter of Nazarenko et al. with non-extendible reporter of Tyagi et al. thereby permitting analysis of an amplification reaction in real time for the obvious benefits of sensitive amplification analysis within a sealed tube as taught by Tyagi et al (Abstract).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 48, 51-55 and 60 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-16 of U.S. Patent No. 6,277,582. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to sets (kits) of oligonucleotides comprising unlabeled primers and reporter probes. The claim sets differ in that the '582 probes and primers are identified by "SEQ ID NO:" while the instant probe and primers are defined by structure i.e. primers have a 5' adapter sequence and probes have a 5' label. However, the '582 specification defines the primer sequences as including adapters i.e. tails (Column 1, line 50-Column 2, line 27). Therefore, the instantly claimed primers and probe are generic to the SEQ ID NO's of the '582 patent.

The courts have stated that a genus is obvious in view of the teaching of a species see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed probes and primers (i.e. genus) are obvious in view of the '582 SEQ ID NO's (i.e. species).

13. Claims 48, 51-55 and 60 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-16 of U.S. Patent No. 6,261,785. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to sets (kits) of oligonucleotides comprising unlabeled primers and reporters. The claim sets differ in that the '785 primers are identified by "SEQ ID NO:" while the instant probe and primers are defined by structure i.e. primers have a 5' adapter sequence and probes have a 5' label. However, the '785 specification defines the primer sequences as including adapters i.e. tails (Column 1, line 45-Column 2, line 24). Therefore, the instantly claimed primers and probe are generic to those of the SEQ ID NO's of the '785 patent and hence the instant genus is obvious.

14. Claims 48, 51-55 and 60 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-15 of U.S. Patent No. 6,251,609. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to sets (kits) of oligonucleotides comprising unlabeled primers and reporters. The claim sets differ in that the '609 primers are identified by "SEQ ID NO:" while the instant probe and primers are defined by structure i.e. primers have a 5' adapter sequence and probes have a 5' label. However, the '609 specification defines the primer sequences as including adapters i.e. tails (Column 1, line 45-Column 2, line 24). Therefore, the instantly claimed primers and probe are generic to those of the SEQ ID NO's of the '609 patent and hence the instant genus is obvious.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic

Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
September 12, 2006